510(k) Summary

Medi-Globe Balloon Dilatation Catheter

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1190 and 21 CFR, Section 807.92.

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JAN 2 1 2003

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Date Submitted: March 2, 2001

Device Name: Balloon Dilatation Catheter

Trade Name: Expander

Common Name: Dilation Balloon

Classification Name: Esophageal Dilator, Biliary Catheter, Endoscopic Accessory

Substantial Equivalence: The Medi-Globe balloon dilatation catheter is substantially equivalent to the balloon catheters manufactured and sold by Boston Scientific (K974788 and K973113).

Device Description: The balloon dilatation catheter is a nylon balloon mounted on a double lumen catheter. Proximately the device is fitted with either one or two luer fittings. The balloon dilatation catheters with balloon diameters larger than 12 millimeters have only one luer fitting that allows for balloon inflation. Balloon dilatation catheters with balloon diameters smaller than 12

millimeters have two luer fittings, one for passage of a guide wire and the other for balloon inflation.

Intended Use: The Medi-Globe balloon dilatation catheters are intended to be used for endoscopic dilation of biliary tract, esophageal or sphincter stenosis.

Comparison to Predicate Device: Please see table on following page.

Conclusion: Medi-Globe Corporation believes its balloon dilatation catheter is substantially equivalent to the currently marketed predicate devices. The table on the following page compares the characteristics of the products and demonstrates equivalence in intended use, design and materials. Additionally, Medi-Globe Corporation has provided laboratory testing demonstrating the product can be safely used for its intended purposes.

Characteristics	**Medi-Globe**	**Boston Scientific**	**Boston Scientific**
510 (k) number	this application	K974788	K973113
Application	Endoscopic dilatation of biliary, esophageal and sphincter stenosis.	⇦Same	⇦Same
Balloon Specifications			
Diameter	4 – 18 mm	6 - 25 mm	4 - 14 mm
Length	2.0 – 8.0 cm	5.5 – 8.0 cm	2.5 – 4.0 cm
Max. Recommended Pressure	3 – 18 atm	2 - 6 atm	9 - 12 atm
Catheter Specifications			
Diameter	5.7 Fr. Tapers to 3 Fr.	7 Fr. Tapers to 5 Fr.	5.8 – 7.8 Fr.
Length	200 cm	180 - 240 cm	180 cm
Balloon Material*	Nylon 11	Polyurethane	Polyurethane
Sterilization	Sterile Packed Single Patient Use	⇦Same	⇦Same
Packaging	Individual Packed Peel-open Pouches	⇦Same	⇦Same

*The only technologic difference between the Medi-Globe and Boston Scientific devices is the material used for the balloon. Medi-Globe's use of nylon 11 for the balloon material has been shown to be safe through both biologic and bench testing studies. Independent toxicology, chemical analysis and cytotoxicity testing has been performed on the completed catheter, including the balloon. This testing found all material to be safe. Testing data can be found in attachment E. Bench testing data demonstrates the balloon's burst pressure is significantly higher than the maximum recommended balloon pressures provided to clinicians. This testing data is found in attachment G.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 21 2003

Mr. Gerhardt Seiwerth
Product Specialist
Medi-Globe Corporation
Medi-Globe Strasse 1-5
D-83101 Achenmühle
GERMANY

Re: K010714
Trade/Device Name: Balloon Dilatation Catheter
Regulation Number: 21 CFR §876.5365
Regulation Name: Esophageal dilator
Product Code: 78 KNQ
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Product Code: 78 FGE
Regulatory Class: II
Dated: October 17, 2002
Received: October 23, 2002

Dear Mr. Seiwerth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K010714

DEVICE NAME: Balloon Dilatation Catheter

INDICATIONS FOR USE:

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The Medi-Globe Balloon Dilatation Catheters are intended to be used for Endoscopic Dilation of Biliary Tract, Esophageal or Shincter Stenosis.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter-Use (Optional Format 1-2)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K010714